



10-09-03

CASE 4-30400B

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EL987586847 US

Express Mail Label Number

October 8, 2003

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

O'REILLY ET AL.

APPLICATION NO: 10/633,114

FILED: AUGUST 1, 2003

FOR: CANCER TREATMENT WITH EPOTHILONES

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the filing date of the application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

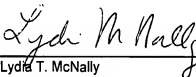
In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

The listed references are of record in parent Application No. 09/925,119 filed August 9, 2001, and copies are available therein. However, applicants are willing to send copies of any or all of these references at the Examiner's request.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

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Date: Oct 8, 2003

## INFORMATION DISCLOSURE CITATION

(Use a vertical line to separate citations if necessary)

ATTY. DOCKET NO.  
4-30400/B  
APPLICATION NO.  
10633,114  
APPLICANT  
O'REILLY ET AL.  
FILING DATE  
August 1, 2003

Group



## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
AA	6,302,838B1	10/16/01	O'Reilly et al.			
AB						
AC						
AD						
AE						
AF						
AG						
AH						

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES	NO
AI	WO 98/25929	6/18/98	PCT			<input type="checkbox"/>	<input type="checkbox"/>
AJ	WO 99/01124	1/14/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
AK	WO 99/02514	1/21/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
AL	WO 97/19086	5/29/97	PCT (w/ English abstract)			<input type="checkbox"/>	<input type="checkbox"/>
AM	WO 93/10121	5/27/93	PCT (w/ English abstract)			<input type="checkbox"/>	<input type="checkbox"/>
AN	41 38 042	5/27/93	Germany (w/ English abstract)				
AO	WO 9907692	2/18/99	PCT (w/ English abstract)				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AP	Balog et al., Tetrahedron Lett., Vol. 38(26), "Stereoselective Syntheses and Evaluation of Compounds in the 8-Desmethylepothilone A Series: Some Surprising Observations Regarding Their Chemical and Biological Properties," pp. 4529-4532 (1997)
AQ	Blagosklonny et al., Cancer Res., Vol. 57, "Raf-1/bcl-2 Phosphorylation: A Step from Microtubule Damage to Cell Death," pp. 130-135 (1997)
AR	Bollag et al., Cancer Res., Vol. 55, "Epothilones, a New Class of Microtubule-stabilizing Agents with a Taxol-like Mechanism of Action," pp. 2325-2333 (1995)

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

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AA	Bollag, D.M., Exp. Opin. Invest. Drugs, Vol. 6(7), "Epothilones: novel microtubule-stabilising agents," pp. 867-873 (1997)
AB	Chou et al., Proc. Natl. Acad. Sci. USA, Vol. 95, "Desoxyepothilone B: An efficacious microtubule-targeted antitumor agent with a promising in vivo profile relative to epothilone B," pp. 9642-9647 (1998)
AC	Finlay, R., Chemistry & Industry, "Metathesis vs. metastasis: the chemistry and biology of the epothilones," pp. 991-996 (December 15, 1997)
AD	Gerth et al., J. Antibiotics, Vol. 49, "Epothilones A and B: Antifungal and Cytotoxic Compounds from Sorangium cellulosum (Myxobacteria) - Production, Physico-chemical and Biological Properties," pp. 560-563 (1996)
AE	Giannakakou et al., J. Biol. Chem., Vol. 27, "Paclitaxel-resistant Human Ovarian Cancer Cells Have Mutant $\beta$ -Tubulins That Exhibit Impaired Paclitaxel-driven Polymerization," pp. 17118-17125 (1997)
AF	Grever et al., Seminars in Oncol., Vol. 19(6), "The National Cancer Institute: Cancer Drug Discovery and Development Program," pp. 622-638 (1992)
AG	Höfle et al., Angew. Chem., Vol. 108(13/14), pp. 1671-1672 (1996) (translated portion stapled to top of this article)
AH	Jordan et al., Med. Res. Rev., Vol. 18, "Tubulin as a Target for Anticancer Drugs: Agents Which Interact with the Mitotic Spindle," pp. 259-295 (1998)
AI	Kowalski et al., J. Biol. Chem., Vol. 272(4), "Activities of the Microtubule-stabilizing Agents Epothilones A and B with Purified Tubulin and in Cells Resistant to Paclitaxel (Taxol®)," pp. 2534-2541 (1997)
AJ	May et al., Chemical Communication, "Total synthesis of (--) -epothilone B," pp. 1597-1598 (1998)
AK	Moasser et al., Proc. Natl. Acad. Sci. USA, Vol. 95, "Farnesyl transferase inhibitors cause enhanced mitotic sensitivity to taxol and epothilones," pp. 1369-1374 (1998)
AL	Mühlradt et al., Cancer Research, Vol. 57, "Epothilone B Stabilizes Microtubuli of Macrophages Like Taxol without Showing Taxol-like Endotoxin Activity," pp. 3344-3346 (1997)
AM	Nicolaou et al., Nature, Vol. 387, "Synthesis of epothilones A and B in solid and solution phase," pp. 268-272 (1997)
AN	Nicolaou et al., Angew. Chem. Int. Ed., Vol. 36(19), "Designed Epothilones: Combinatorial Synthesis, Tubulin Assembly Properties, and Cytotoxic Action against Taxol-Resistant Tumor Cells," pp. 2097-2103 (1997)

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AA	Nicolaou et al., <i>Angew. Chem. Int. Ed.</i> , Vol. 37, "Chemical Biology of Epothilones," pp. 2014-2045 (1998)
AB	Nicolaou et al., <i>Chemistry &amp; Biology</i> , Vol. 5(7), "Synthesis and biological properties of C12, 13-cyclopropyl-epothilone A and related epothilones," pp. 365-372 (1998)
AC	Su et al., <i>Angew. Chem. Int. Ed.</i> , Vol. 36(7), "Total Synthesis of (-)-Epothilone B: An Extension of the Suzuki Coupling Method and Insights into Structure-Activity Relationships of the Epothilones," pp. 757-759 (1997)
AD	Su et al., <i>Angew. Chem. Int. Ed.</i> , Vol. 36(19), "Structure-Activity Relationships of Epothilones and the First In Vivo Comparison with Paclitaxel," pp. 2093-2096 (1997)
AE	Wartmann et al., <i>Proceedings of the Amer. Assn. for Cancer Res.</i> , New Orleans, March 28-31, 1998, Vol. 39, "In vitro and in vivo activity profile of the microtubule-stabilizing agents epothilone A and B," p. 163, Abstract #1118 (1998)
AF	Chou et al., <i>Proceedings of the Amer. Assn. for Cancer Res.</i> , New Orleans, March 28-31, 1998, Vol. 39, "Pharmacologic comparison of epothilones and taxol," pp. 163-164, Abstract #1119 (1998)
AG	Wolff et al., <i>Int. J. Oncol.</i> , Vol. 11, "Epothilone A induces apoptosis in neuroblastoma cells with multiple mechanisms of drug resistance," pp. 123-126 (1997)
AH	Fojo et al., <i>Cancer Res.</i> , Vol. 45, "Reduced Drug Accumulation in Multiply Drug-resistant Human KB Carcinoma Cell Lines," pp. 3002-3007 (1985)
AI	Akiyama et al., <i>Somatic Cell and Molecular Genetics</i> , Vol. 11, No. 2, "Isolation and Genetic Characterization of Human KB Cell Lines Resistant to Multiple Drugs," pp. 117-126 (1985)
AJ	Meyer et al., <i>Int. J. Cancer</i> , Vol. 43, "A Derivative of Staurosporine (CGP 41 251) Shows Selectively for Protein Kinase C Inhibition and <i>In Vitro</i> Anti-Proliferative as well as <i>In Vivo</i> Anti-Tumor Activity," pp. 851-856 (1989)
AK	Bradley D., <i>Drug Discovery Today</i> , Vol. 2(3), "Race to displace Taxol," pp. 87-88 (1997)
AL	Cowden C., and Paterson, I., <i>Nature</i> , Vol. 387, "Cancer drugs better than taxol?", pp. 238-239 (1997)
AM	Höfle G. et al., <i>Angew. Chem. Int. Ed. Engl.</i> , Vol. 35 (13/14), "Epothilone A and B - Novel 16-Membered Macrolides with Cytotoxic Activity: Isolation, Crystal Structure, and Conformation in Solution," pp. 1567-1569 (1996)
AN	König J., <i>Pharmazeutische Zeitung</i> , Vol. 142 (8) "Epothilone, ein neuer Wirkstoff gegen Krebs?" p. 35 (English translation attached)
	Mann J., <i>Nature</i> , Vol. 385, "Myxobacterial bounty," p. 117 (1997)

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